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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,079	03/07/2001	Jorg Rosenberg	0480/001216	1470

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KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

FONTAINE, MONICA A

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,079

Applicant(s)

ROSENBERG ET AL.

Examiner

Monica A Fontaine

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the Amendment filed 24 September 2003.

The following rejections have been overcome:

A. 35 USC 112 (2nd): Claims 4-5, 7-11

B. 35 USC 102(b) as anticipated by Dabal et al. (U.S. Patent 4,072,551),
hereafter "Dabal": Claims 7-9, 11-12

C. 35 USC 103(a) over Dabal, in view of Blanding et al. (U.S. Patent 3,859,407),
hereafter "Blanding": Claims 1-5 and 10

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Since Claim 3 as presented on 21 May 2001 requires a "parallel" force instead of the current "perpendicular" force, and the change from "perpendicular" to "parallel" was not indicated with correct notation in the current Claim 3, the examiner is assuming that a typographical error was made. Therefore, Claim 3 will be examined as requiring a "parallel" force (as indicated in the Amendment filed 21 May 2001).

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klimesch et al. (U.S. Patent 4,880,585), hereafter "Klimesch '585", in view of Klimesch et al. (U.S. Patent 5,073,379), hereafter "Klimesch '379". Regarding Claim 1, Klimesch '585 shows that it is known to carry out a process for producing tablets by melt extrusion, in which an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip (Figure 1; Column 2, lines 64-67), the still deformable product strip is compressed to a continuous tablet belt (Figure 1; Column 1, lines 62-67), the individual tablets in the belt being connected together by product webs (Figure 1; Column 1, lines 62-67), the tablet belt being allowed to cool to form a solidified tablet belt (Column 2, lines 16-21), and the tablets are transported further and subsequently deflashed (Column 2, lines 2-7). Klimesch '585 does not show a continuous singulation process. Klimesch '379 shows that it is known to singulate a tablet belt in a continuous process (Figure 1; Column 11, lines 8-9). Klimesch '379 and Klimesch '585 are combinable because they are concerned with a similar technical field, namely, that of extruding pharmaceutical mixtures to form tablets. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to continuously

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singulate Klimesch '585's tablets, as in Klimesch '379, in order to reduce the amount of space needed to transport the molded tablets to the deflashing site.

Regarding Claims 2 and 3, Klimesch '585 shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a directional force acting to singulate each tablet. Klimesch '379 shows that it is known to carry out a method wherein a force with a component perpendicular and parallel to the plane of the tablet belt is allowed to act on the tablet for singulation of the tablet(s) (Figure 1; Column 2, lines 61-63; It is noted that the perpendicular component causes the tablets to be propelled downward and the parallel component causes the tablets to be advanced in the direction of extrusion.). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's perpendicular and parallel forces to tabulate Klimesch '585's belt in order to avoid the need for sharp edges for cutting purposes.

Regarding Claim 4, Klimesch '585 shows the process as claimed as discussed in the rejection of Claims 1 and 2 above, but he does not show a directional force that diverts the tablet belt in a specific direction. Klimesch '379 shows that it is known to carry out a method wherein the perpendicular force component is generated by diverting the solidified tablet belt out of its transport plane (Figure 1; Column 2, lines 61-67). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's diverting force to tabulate Klimesch '585's belt in order to avoid the need for sharp edges for cutting purposes.

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Regarding Claim 5, Klimesch '585 shows the process as claimed as discussed in the rejection of Claims 1 and 2 above, but he does not show a directional force acting to singulate each tablet. Klimesch '379 shows that it is known to carry out a method wherein the parallel force component is generated by exerting a traction force on the solidified tablet belt (Figure 1; Column 11, lines 9-14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's parallel traction force to help tabulate Klimesch '585's belt in order to avoid the need for sharp edges for cutting purposes.

Regarding Claim 12, Klimesch '585 shows that it is known to use an apparatus for producing tablets (Figure 1), comprising at least one extruder (Figure 1, element 1), means for shaping a tablet belt arranged downstream of said extruder means for heating a pharmaceutical mixture (Figure 1, element 5), first transport means for said tablet belt comprises means for cooling the extruded tablet belt and which is arranged downstream of said shaping means (Column 1, lines 67-68; Column 2, lines 1-7, 16-21), means deflashing said tablets arranged downstream of singulating means and spatially separate therefrom (Column 2, lines 1-7). Klimesch '585 does not show a means for continuous singulation. Klimesch '379 shows that it is known to have means to singulate a tablet belt in a continuous process (Figure 1; Column 11, lines 8-9). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the means to continuously singulate Klimesch '585's tablets, as in Klimesch '379, in order to reduce the amount of space needed to transport the molded tablets to the deflashing site.

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Regarding Claim 7, Klimesch '585 shows the process as claimed as discussed in the rejection of Claim 12 above, but he does not show a diverting singulating means. Klimesch '379 shows that it is known to have an apparatus including singulating means which comprise at least one rotatable roller for diverting the tablet belt out of a transport plane of a transport means (Figure 1). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's diverting force to tabulate Klimesch '585's belt in order to avoid the need for sharp edges for cutting purposes.

Regarding Claim 8, Klimesch '585 shows the process as claimed as discussed in the rejection of Claims 12 and 7 above, but he does not show roller singulation means. Klimesch '379 show that it is known to have an apparatus including singulation means which comprise two counter-rotating rollers which can be pressed against one another (Figure 1). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's counter-rotating roller singulation means to tabulate Klimesch '585's belt in order to avoid the need for sharp edges for cutting purposes.

Regarding Claim 9, Klimesch '585 shows the process as claimed as discussed in the rejection of Claim 12 above, but he does not show the use of a singulation means of a brush roller or embossed roller. Klimesch '379 shows that it is known to have an apparatus including singulation means comprising a brush roller or an embossed roller (Column 2, lines 32-34, 61-68). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Klimesch '379's brush or embossed roller in order to singulate Klimesch '585's belt in order to impart decoration on the singulated tablet and/or to simultaneously clean the mold while singulating the tablet belt.

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Regarding Claim 11, Klimesch '585 shows the process as claimed as discussed in the rejection of Claim 12 above, including transport packaging means (Column 2, lines 3-7). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a shaking unit while packaging the tablets in order to compress their volume and reduce the amount of packaging needed to ship the tablets to further processing.

Response to Arguments

Applicant's arguments, see Paper No. 7, filed 5 September 2003, with respect to the rejection(s) of claim(s) 1-5, and 7-12 under Dabal and Blanding have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Klimesch '585 and Klimesch '379.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 703-305-7239. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Colaianni can be reached on 703-305-5493. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maf

Maf

December 4, 2003

*new phone number
after 12/22/03
571-272-1198*



**MICHAEL COLAIANNI
PRIMARY EXAMINER**